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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,292	03/27/2001	Achim Berthold	R00212US(#90	7217

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EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/743,292	BERTHOLD, ACHIM	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Request for Continued Examination (RCE) under 37 CFR 1.114 filed 09/24/04 and the Amendment and Applicant's Arguments/Remarks, both filed 04/19/04 is acknowledged.

Claims 1-28 are pending. Claims 1, 14 and 15 have been amended. Claims1-28 are rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kwiatek *et al.* (US Pat. No. 5,503,844).

Kwiatek *et al.* teach a transdermal therapeutic patch for the controlled release of lovastatin to the skin or mucous membranes, wherein the transdermal patch contains active substance(s), a backing layer, active agent permeable adhesive layer(s), rate-controlling polymers and means whereby the transdermal patch has a high degree of uniformity and consistency for critical transdermal properties such as release rate (see reference column 1, line 45 through col. 2, line 25); (col. 11, line 47 through col. 12, line 55); (col. 16, lines 30-40); (column 17, lines 5-12); (column 24, lines 20-26).

Kwiatek teaches that each active agent permeable adhesive layer is a pressure-sensitive adhesive. Any of the well-known, dermatologically acceptable, pressure-sensitive adhesives that permit drug migration therethrough can be used (col. 11, lines 40-46). Suitable permeable adhesives include acrylic or methacrylic resins, polyisobutylene pressure-sensitive adhesives, rubber pressure-sensitive adhesives, silicon pressure-sensitive adhesives and the like. Additionally, tackifiers, stablilizers, active agent flux enhancers, carriers, binders, etc. may also be used in the patch (col. 11, line 47 thru col. 12, line 4); (col. 17, lines 29-67); (col. 18, lines 1-22).

According to Kwiatek, the rate of permeation of the active agent through the rate-controlling polymer layer depends upon factors such as the affinity of the active agent for the polymer layer, molecular size of the active agent, polymeric structure of the foam layer and the thickness of the layer. Therefore, the appropriate rate-controlling polymeric material and its thickness depend on the active agent used and the desired rate of permeation. The selection of a

polymer layer and its thickness provides a means if desired, for controlling the dosage rate to the skin or mucosa, and is essentially conventional to those of ordinary skill in the art (col. 16, lines 30-40).

The active agent permeable adhesive layers preferably contain some of the active agent when the device is placed on the skin. This provides an initial active agent presence at the skin or mucosa and eliminates delay in absorption of the active agent if desired (col. 12, lines 38-52).

Kwiatek teaches in Table 1, col. 22, up to a 24-hour release profile of nicotine flux through the skin and teaches theory of how to control the rate of release.

Regarding release rates, Kwiatek teaches that the transdermal patch is produced efficiently with little variation in release rate. Furthermore, the patch offers uniformity and consistency for release rate properties (col. 1, lines 45-60).

There is no significant distinction observed between the instant invention and the prior art since the prior art clearly teaches a transdermal therapeutic patch containing an active ingredient which influences blood lipid levels, lovastatin, wherein the patch comprises a backing layer, active agent permeable adhesive layer(s), rate-controlling polymers wherein the active agent is contained within the pressure-sensitive adhesive layers. Kwiatek teaches that the active agent can be contained in the active agent permeable adhesive layers and in the cellular foams that are suitable for use as carrier layers for active agents in transdermal patches (col. 1, line 54 – col. 2, line 25). Furthermore, Kwiatek clearly teaches a release profile of up to 24-hours and also teaches the theory of how to control rates of release and consistency of release rates. Hence, the instant invention is rendered obvious and unpatentable over the prior art.

Response to Arguments

Applicant's arguments filed 04/19/04 have been fully considered but they are not persuasive.

Firstly, Applicant argued regarding the 35 USC 103(a) rejection of claims 1-15 over Kwiatek stating, "Claims 1 and 15 pertain to a transdermal therapeutic system in the form of an adhesive patch in which the active substance is incorporated into the adhesive layer, and the side of the adhesive layer which faces away from the skin is covered with an active substance-impermeable backing layer. The applicant submits from this, it clearly follows that the adhesive layer is the one and only reservoir (for active substances) in the claimed transdermal system. The wordings of claims 1 and 15 exclude the possibility of an additional foam-type reservoir, as described in Kwiatek. The side of the adhesive layer which faces away from the skin is *not* covered with an active substance-impermeable backing layer, but with a cellular foam layer which contains most of the active substance and which is permeable to the active substance."

These arguments have been fully considered, but were not persuasive. Applicant's argument that the 'wordings of claims 1 and 15 exclude the possibility of an additional foam-type reservoir' is not persuasive since the instant claim language does permit the inclusion of additional layers and ingredients asides from those recited in the instant claims. Kwiatek teaches that the active ingredient is contained in the foam and also in the permeable adhesive layers. Although, the side of the adhesive layer which faces away from the skin is covered with a cellular foam layer in Kwiatek, Applicants have not demonstrated any criticality or unexpected/unusual results that accrue from the covering of the polymer matrix layer with active

substance-impermeable backing layer. The prior art teaches the delivery of active substances, which include drugs affecting blood serum levels, whereby the active substances are also contained in the adhesive layers.

Secondly, Applicant argued, "Claims 1 and 15 provide that essentially all of the active substance, which is to be released from the transdermal system is present within the adhesive matrix layer. In contrast, in the trandsdermal patches of Kwiatek, only a small portion of the total amount of active substance is present in the active substance-permeable matrix layer. The bulk of the active substance in '844 is contained in the foam matrix layer."

This argument was not persuasive since the instant claims are not limited to any particular or specific amounts of active substance content that can or cannot be contained therein. The instant generic claims are broad in nature and are not directed to any specific amounts with any specific formulations.

Thirdly, Applicant argued, "Nothing in Kwiatek suggests that the foam layer could be omitted or that an active agent permeable adhesive layer could be used as the sole active substance reservoir. The invention of Kwiatek was made to provide a better method for making transdermal patches which contain liquid active substances, such as nicotine."

Applicant's arguments were not found persuasive. As delineated above, the instant invention does not exclude the possibility of additional layers. Moreover, the prior art teaches the effective transdermal delivery of various active agents in a suitable manner, and therefore the additional layer taught by Kwiatek would not be deemed detrimental or adverse in nature to the transdermal formulation itself. Regarding liquid or solid active substances, it is the Examiner's

position that the prior art is not limited only to the examples taught therein. The prior art clearly teaches the inclusion of solid active substances, as well as liquid.

Applicant argued, "In view of the teaching of Kwiatek, the observation that the release of active substance is essentially constant over a period of at least 72 hours when using an adhesive reservoir instead of a foam reservoir is unexpected. Moreover, the conclusion that such a result would be obvious in the system of Kwiatek would be applying impermissible hindsight reasoning."

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Lastly, Applicant argued, "The reference provides no suggestion or motivation to modify the invention of Kwiatek to make up for the aforementioned deficiencies, nor would there be a reasonable expectation of success if one skilled in the art were to attempt to modify the reference."

These arguments were not persuasive. Ample motivation is provided by the prior art to utilize transdermal formulations to deliver active substances that influence blood lipid levels (*i.e.* lovastatin). Moreover, the prior art patches provide for uniformity and consistency of release

rates, as similarly desired by Applicants. Thus, the instant invention is rendered *prima facie* obvious over the cited art of record.

Relevant Art Citations

US Pat. No. 6,024,976 Miranda *et al.* (02/2000)

Made of record and considered relevant by examiner.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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H. N. Sheikh HNS

Patent Examiner

Art Unit 1615

January 10, 2005

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